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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Friedbert Wechs

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02/03/2009

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EXAMINER

CHRISTIAN, MARJORIE ELLEN

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,696	Applicant(s) WECHS ET AL.	
	Examiner MARJORIE CHRISTIAN	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/29/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/8/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed October 29th, 2008 has been entered and fully considered.
2. The objections to the information disclosure statement are withdrawn in light of Applicant's submission of concise explanations of relevance and clarification.
3. The objections to the oath/declaration have been withdrawn as unnecessary per 37 CFR 1.55 as no intervening reference is present.
4. The objections to the specification have been withdrawn in light of Applicant's amendments.
5. The rejections under 35 USC 112, 2nd Paragraph are withdrawn in light of Applicant's amendments.
6. Claims 1-20 are pending and have been fully considered.

Double Patenting

7. Claims 1-9, 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/588,695. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claim 1 has an ultrafiltration rate in albumin solution in the range of 5 to 23.5 ml/(h.m².mmHg) , whereas the copending claim 1 has an ultrafiltration rate in the range of 25 to 60 ml/(h.m².mmHg). However, it appears that the apparatus in the instant claims would function at a higher ultrafiltration rate as there is no structural difference between the

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membranes. The sieving coefficient of cytochrome c in the instant claim 1 is expressed by a relation, whereas the copending claims discloses the sieving coefficient of cytochrome c as a minimum of 0.8. Using the ultrafiltration rate range disclosed by the copending claim 1, the relation disclosed by the instant claim 1 was satisfied in that it is higher 0.8. As further evidence that the copending and instant claims overlap in scope, and therefore are not patentably distinguishable, the instant specification discloses that the minimum sieving coefficient for cytochrome c is preferably 0.8 (Page 11, Lines 1-2). Therefore the sieving coefficient disclosed by the copending application claim 1 are within range of the relation disclosed in the instant claim 1. Instant claims 3-9 are identical to copending claims 2-10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

8. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 fails to further limit claim 1, and in fact broadens the upper limit of the ultrafiltration rate in albumin solution from 23.5 ml/(h.m².mmHg) to 25 ml/(h.m².mmHg) .

Claim Rejections - 35 USC § 102

9. **Claims 1, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by SLUMA et al. US Patent No. 5,290,448 (hereinafter SLUMA).**

As to Claims 1, 9, 11, SLUMA discloses a semi-permeable membrane in the form of a hollow fiber (Abstract) comprising: a synthetic first polymer possessing an open-pored integrally asymmetric structure across its wall (Figures 2-5); the skin has a thickness of 0.1 to 0.2 microns on the inside of the cavity (SLUMA, Claim 3) ***[porous separating layer of thickness between 0.1 and 2 μ m on the inner surface facing the lumen]***; an ultrafiltration rate in albumin solution of 13 mL/(m².h.mmHg) (Example 3); and the albumin screen coefficient is 0 (Example 3) ***[maximum sieving coefficient for albumin of 0.003]***. The limitation “where no additives are present and properties were measured after drying” is only a caveat and does not structurally differentiate the apparatus, further the apparatus has the desired sieving co-efficient even in the presence of these additives (Example 1, C4/L13-14) ***[in absence of additives stabilizing the pores in the membrane wall and after prior drying]***. The screen coefficient in Example 3 satisfies the relation for the sieving coefficient of cytochrome c shown below.

$$SC_{cc} \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}^3 - 0.004 \cdot UFR_{Alb}^2 + 0.1081 \cdot UFR_{Alb} - 0.25$$

$$0.61(SC_{cc}) \geq 0.59$$

Claim Rejections - 35 USC § 102/103

10. **Claims 1-9, 11**, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6,565,782, WANG et al. (hereinafter WANG).

As to Claims 1-9, WANG discloses a hydrophilic, water-wettable, semi-permeable hollow-fiber membrane for blood purification (Abstract) comprising a synthetic first polymer (Example 1), the hollow-fiber membrane possessing an open-pored integrally asymmetric structure across its wall (Abstract, Figs. 1A-C), a porous separating layer and an open-pored supporting layer adjoining the separating layer (C3/L14-31) characterized in that there is an absence of additives stabilizing the pores in the membrane wall and after prior drying (Example 1). WANG does not appear to expressly disclose that the skin has a thickness of 0.1 to 2 microns, ultrafiltration rate in albumin solution, maximum sieving co-efficient of albumin and relation for the sieving coefficient of cytochrome c. However, WANG discloses a hollow fiber made of the same material, polysulfone and polyvinylpyrrolidone (C7/L51-57) (instant Claims 3-7); supporting layer that extends from the separating layer across essentially the entire wall of the hollow-fiber membrane (C3/L13-31) and has a sponge-like structure that is free from finger pores (Fig. 1C, 2A) (instant Claims 8); and similar process of making (WANG, Example 1, Claim 1). It is therefore inherent that the hollow fiber has an ultrafiltration rate in albumin solution of 10 to 23.5 ml/(h.m².mmHg), maximum sieving

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coefficient for albumin of 0.003, and sieving coefficient for cytochrome c satisfies the relation (shown below), absent evidence to the contrary.

$$SC_{cc} \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}^3 - 0.004 \cdot UFR_{Alb}^2 + 0.1081 \cdot UFR_{Alb} - 0.12$$

Claim Rejections - 35 USC § 103

11. **Claims 3-8 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,290,448 SLUMA et al. (hereinafter SLUMA) in view of US Patent No. 4,906,375, HEILLMAN (hereinafter HEILMANN).**

As to Claims 3-8, SLUMA discloses the semi-permeable membrane in the form of a hollow as shown above in the 102(b) rejection of Claim 1. SLUMA does not appear to expressly disclose the use of hydrophobic and hydrophilic polymers. However, HEILMANN discloses that the microporous hollow fiber is made up of a first hydrophobic polymer and second hydrophilic polymer (Abstract) specifically polysulfone (C4/L44-46 and polyvinylpyrrolidone (C5/L17-18) and that next to microporous barrier layer on the outside is a foam-like supporting structure that is different to the lamellae-like structures of the prior art (C9/L51-54) ***[supporting layer extends from the separating layer across essentially the entire wall of the hollow-fiber membrane and has a sponge-like structure that is free from finger pores]***.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the hollow fiber of SLUMA to include the hydrophilic and hydrophobic polymers of HEILMANN. The motivation would have been to have a hollow fiber with very good hydraulic permeability and excellent mechanical strength (HEILMANN,

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C3/L55-57). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

12. Applicant's arguments filed October 29th, 2008 have been fully considered.

Applicant argues that against the provisional non-statutory obviousness type double patenting rejection, stating that the test methods for determining the ultrafiltration rates in albumin solution are different and by amending claim 1 to have different ultrafiltration rates from the copending application. This is not found persuasive as the structure recited is the same, especially given that the formula for determining the ultrafiltration rates is identical. Different ultrafiltration ranges and test methods are not significant in establishing that the structure as recited in the claims and examples are patentably different.

Applicant's argument that the polymer disclosed by SLUMA is hydrophobic is not found persuasive. As SLUMA discloses that the copolymer includes acrylic ester (Abstract) which indicates that it is *hydrophilic*.

Applicant's argument that SLUMA does not disclose the limitation "the absence of additives stabilizing the pores in the membrane wall and after prior drying" is not found persuasive. This is merely a caveat not a structural limitation and implies that the presence of additives inhibits the membranes ability to meet the sieving coefficient relation for cytochrome c. SLUMA provides evidence (102(b) rejection of Claim 1) that the sieving coefficient for cytochrome c is met even in the presence of additives.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that in the combination of SLUMA and HEILMANN, HEILMANN does not satisfy the relation for the sieving coefficient of cytochrome c is not found persuasive. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Allowable Subject Matter

13. Claims 12-20 are allowed. The combination of a polyelectrolyte as the interior filler in the steps of producing a hollow fiber with a sieving coefficient for cytochrome c that satisfies the relation specified is novel.

Claim 1 would be allowed if rewritten to include the limitations of Claims 2 and 10, upon filing of a terminal disclaimer to remove the non-statutory obviousness-type double patenting rejection and adjusting the upper limit of the ultrafiltration range in Claim 11 to be commensurate in scope with Claim 1. The following is a statement of reasons for the indication of allowable subject matter: the cytochrome c sieving coefficient limitation in claim 2 in combination with the polyelectrolyte of claim 10 in the hollow fiber is novel.

Examiner Initiated Interview Summary

14. Claims 1-11 are provisionally rejected for non-statutory obviousness-type double patenting, Claims 12-20 are allowable. Apparatus claims (1-11) would be indicated allowable if Applicant includes claim 2 and claim 10 with claim 1. Applicant has option of cancelling claims 1-11 to overcome requirement for terminal disclaimer and claims 12-20 will be allowed, OR filing a terminal disclaimer with the amendment proposed above would place the apparatus claims (1-11) in condition for allowance in conjunction with claims 12-20. Applicant requested an office action be sent.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MC

/Krishnan S Menon/
Primary Examiner, Art Unit 1797